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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,000	03/24/2005	Noriyuki Sato	0020-5360PUS1	4504

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EXAMINER	
LI, QIAN JANICE	

ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
08/04/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/529,000	SATO ET AL.	
	Examiner	Art Unit	
	Q. JANICE LI, M.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *8-18 and 21-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,19,20,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-7, 19 and 20, drawn to SEQ ID No: 2, and species election drawn to SEQ ID No: 6 is acknowledged. The traversal is on the ground(s) that SEQ ID Nos: 6-36 are subsequences of SEQ ID No: 2, hence, the subsequences are species. Also claims 25 and 26 depend from claims 19 and 20. The arguments are persuasive. Accordingly, SEQ ID Nos: 2 and 6 will be examined together. Claims 7-36 will be rejoined upon allowance of the generic claims.

Claims 1-26 are pending, however, claims 8-18, 21-24 are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. Claims 1-7, 19, 20, 25 and 26 are under current examination.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (for example, pages 12, 32, 52). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

Claims 25 and 26 are objected to because they encompass more than one inventions as defined in the Restriction requirement, upon election of an invention for examination, said claims should be amended so that it only reads upon the elected invention. The claims will be examined to the extent that they read on the elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 19, 20, 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite "substantially the same amino acid sequence as shown in SEQ ID No: 2". The specification does not define the range of variations embrace by the phase "substantially the same", and thus the metes and bounds of the claims are uncertain.

Claim 2 is vague and indefinite because the claimed peptide may be interpreted as a fragment of SEQ ID No: 2 or a full-length SEQ ID No: 2, which is a partial peptide of another protein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 7, 19, 20, 25 and 26 are rejected under 35 U.S.C. 102(a) as being anticipated by *Boeckle et al* (Virol 2002;293;103-117, IDS).

Boeckle discloses a peptide having the same amino acid sequence as shown in the instant SEQ ID No: 2, and partial peptide thereof (e.g. pages 104, 106, 108), which comprises an amino acid sequence as shown in SEQ ID No: 6 and more than 8 contiguous amino acids of SEQ ID No: 2. The properties as recited in claims 2 and 3 describe an intrinsic property of SEQ ID No: 2. Accordingly, *Boeckle* anticipates instant claims.

Please note that the claim recitation "an inducer of CTL" or "a tumor marker" has not been given patentable weight in this rejection and rejections that follow. This is because the use of a product for a particular purpose is not afforded patentable weight in a product claim where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand alone. The MPEP states that,".. in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." In re Casey, 152 USPQ 235 (CCPA 1967); In re Otto , 136 USPQ 458, 459 (CCPA 1963)(MPEP 2111.02).

Claims 1-4, 6, 7, 19, 20, 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by *Tang et al* (*WO* 01/55437).

Tang discloses a peptide (SEQ ID No; 222) having the same amino acid sequence as shown in the instant SEQ ID No: 2, which comprises an amino acid sequence as shown in SEQ ID No: 6 and more than 8 contiguous amino acids of SEQ ID No: 2. The properties as recited in claims 2 and 3 describe an intrinsic property of SEQ ID No: 2. Tang also teaches using the polypeptide and segments for detection/diagnosis. Accordingly, *Tang* anticipates instant claims.

(Note only relevant portions of the cited WO document, i.e. cover page, Summary of Invention, and Sequence listing for SEQ ID No: 222, are provided for the sake of conservation because the full document exceeds 800 pages).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-4, 6, 7, 19, 20, 25, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Konya et al* (J Gen Virol 1997;78:2615-20), in view of *Boeckle et al* (Virol 2002;293;103-117, IDS).

The claims are directed to a partial peptide of instant SEQ ID No: 2.

Konya teaches identifying CTL epitopes of the HPV-16 E2 protein for developing cancer vaccine, wherein many small peptides were found to contain HLA binding motif

and have CTL-inducing activity (e.g. the abstract, table 1, figure 1). *Konya* does not teach identifying CTL-epitopes of a HPV-8 protein.

Boeckle supplemented *Konya* by establishing it was known in the art that HPV-8 induces benign epithelial tumors of the skin, which may progress to skin carcinoma, hence proteins of HPV-8 would be the subject of investigation for developing HPV-8 vaccine. Accordingly, it would have been *prima facie* obvious to apply the method taught by *Konya* for developing a HPV-8 vaccine by identifying CTL epitopes within the protein as disclosed by *Boeckle* to arrive at the claimed partial peptides.

Accordingly, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Claims 2-4, 6, 7, 19, 20, 25, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over *May et al* (J Gen Virol 1991;72:2989-97).

May investigated topography of DNA-protein interactions in the non-coding region of HPV-8 including the E2-binding proteins and fragments thereof (e.g. page 2991 and fig. 2), wherein at least some of these fragments would comprising the recited fragments.

Accordingly, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Konya et al* (J Gen Virol 2001;82:77-83), in view of *Boeckle et al* (Virol 2002;293;103-117, IDS)

as applied to claims 2-4, 6, 7, 19, 20, 25, 26 above, further in view of *Kubo et al* (J Immunol 1994;152:3913-24).

Claim 5 is directed to a mutant of SEQ ID No: 6, wherein the amino acid residue at position 2 is substituted. The combined teaching of *Konya* in view of *Boeckle* does not mention modifying CTL-inducing peptides.

Kubo et al teaches that most CTLs recognize foreign antigen in association with class I molecules (HLA alleles) in the form of a peptide fragment bound to the MHC class I molecule, wherein the peptides generally comprise 8-10 residues, the binding motif of the peptides for different alleles is allele-specific and well characterized. For example, *Kubo* teaches peptides that specifically bind HLA-A24 displayed anchor residues predicted by a specific motif at position 2 and at the COOH-terminal, regardless of peptide length, and synthetic versions of the naturally processed peptides were shown to bind to the appropriate alleles. *Kubo* teaches the knowledge provides a rational approach to search Ags with epitopes restricted to binding of certain HLA alleles for clinical use (e.g. the abstract, table V).

Accordingly, it would have been suggested to the skilled in the art to design a given antigenic peptide of interest for binding to a specific HLA allele of interest by modifying the peptide so that they comprise a specific binding motif of interest. The ordinary skilled artisan would have been motivated to modify the claimed invention for promoting a desired CTL response in vaccine development. Given the knowledge in the art as taught by *Kubo*, one would have had a reasonable success in modifying

fragments of SEQ ID No: 2. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is **571-272-0730**. The examiner can normally be reached on 9:30 am - 7:30 p.m., Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The **fax** numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

For all other customer support, please call the USPTO Call Center (UCC) at **800-786-9199**.

/Q. JANICE LI, M.D./
Primary Examiner, Art Unit 1633

Q. Janice Li, M.D.
Primary Examiner
Art Unit 1633

July 31, 2008